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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/174,937      | 10/19/1998  | RORY A J CURTIS      | MNI.061             | 6314             |

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LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

BUGAISKY, GABRIELE E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1653

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/174,937

Applicant(s)

CURTIS ET AL.

Examiner

Gabriele E. BUGAISKY

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,8-12 and 27-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41 is/are allowed.
- 6) ☒ Claim(s) 1, 4-5, 8-12, 30-31, 33-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment of 2/19/2003 is acknowledged. Claims 1-2, 4-5, 8-12 and 27-41 remain under consideration.

Applicants remarks regarding piecemeal prosecution are noted. It should be pointed out that the Examiner could in no way anticipate that Applicants would choose to replace reference to hyperlinks by citing references published several years subsequent to the filing date of this application; her only possible response was to raise a new matter objection. With respect to the date discrepancy noted by Applicants, the Examiner usually relies upon the date entered by the staff on the face of the file; the date of facsimile transmission on the papers filed in August is indeed 8/23/2002. Any confusion is regretted.

### ***Specification***

The objection to the amendment of 8/2002 because of new matter is withdrawn, in light of the new amendment, in which no reference is made either to hyperlinks or references published subsequent to the filing date

The disclosure remains objected to because of the following informalities: all of the ATCC Accession Numbers (e.g., page 2, line 33, page 3, lines 27, 32 and 38, etc) have been left blank.. The Examiner notes the remarks by Applicants regarding their right to make a deposit, prior to issuance of the application; the objection must be maintained until allowance and written assurance that the deposits will be made.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 8-12, 34-35 and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the recited nucleic acids which encode protein and whose full complement hybridizes under the recited conditions to the recited SEQ IDs, does not reasonably provide enablement for the recited nucleic acids which encode protein and hybridize under the recited conditions to the recited SEQ ID. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. SEQ ID NOs: 1,3-4, 6-7 and 9 all are the coding sequences for the Nip2 homologues. A single nucleic acid molecule cannot both hybridize to the coding strand and encode protein unless it is a palindrome; Applicants have not enabled such molecules. It is suggested that the claims be amended to state that it is the full complement of the nucleic acid which encodes the NIP2 homologs that hybridizes to the coding nucleic acids

The rejection of claims 1-2 4-5 8-12 29-41 under 35 U.S.C. 112, first paragraph, for new matter is withdrawn.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 9, 27, 37-38, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams *et al.* The reference teaches an EST T08680, which is 437 bases in length and shows 100% identity in nucleotides 1-269 to nucleotides 845-1113 of SEQ ID NO: 3; furthermore, these nucleotides encode aa 283-371 of SEQ ID NO:2, . . . This sequence is deemed anticipatory for the claimed subject matter because the complement of the DNA of reference is 100% identical to instant SEQ ID NO:1, and 3. Please note that the instant claims make no limitation on the size of the complement; amendment to recite “full complement”, e.g., would overcome this rejection for claims -2, 5, 9, and 27. Amendment to recite, e.g., 60% identical to the full length of SEQ ID NO:2 would overcome this rejection for claim 37.

Claims 9, 28, 29, 32, 33, 37-38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank accession no AA5044063. The reference is an EST, which is 275 bases in length and shows 100% identity in nucleotides 3-302 to nucleotides 48-298 of SEQ ID NO: 6; furthermore, these nucleotides encode aa 17-99 of SEQ ID NO:5, . . . This sequence is deemed anticipatory for the claimed subject matter because the complement of the DNA of reference is 100% identical to instant SEQ ID NO:4, and 6. Please note that the instant claims make no limitation on the size of the complement; amendment to recite “full complement”, e.g.,

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would overcome this rejection for claims , 9, 28, 29, and 32 -33. Amendment to recite, e.g., 60% identical to the full length of SEQ ID NO:5 would overcome this rejection for claim 37.

Claims 9, 30, 31, 33, 37-38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujihara *et al.* The reference teaches an EST D61567, which is 302 bases in length and shows 100% identity in nucleotides 3-302 to nucleotides 1-272 of SEQ ID NO: 9; furthermore, these nucleotides encode aa 1-90 of SEQ ID NO:8, . . . This sequence is deemed anticipatory for the claimed subject matter because the complement of the DNA of reference is 100% identical to instant SEQ ID NO:7, and 9. Please note that the instant claims make no limitation on the size of the complement; amendment to recite "full complement", e.g., would overcome this rejection for claims 9, 30, 31, and 33. Amendment to recite, e.g., 60% identical to the full length of SEQ ID NO:8 would overcome this rejection for claim 37.

Claims 1, 5, 8-12, 36, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by RYAN *et al.* The effective filing date of this patent is 9/2/97. Nucleotides 25149-25630 of SEQ ID NO:6 share 81% similarity with nucleotides 2605-3076 of instant SEQ ID NO:1. This sequence is deemed anticipatory for the claimed subject matter of claim 5 because it comprises a nucleic acid whose complement is at least 59% identical to SEQ ID NO:1. Likewise, the complement of portions of nucleotides 25149-25630 of SEQ ID NO:6 of the reference are 100% identical to instant SEQ ID NO:1. Please note that the instant claims make no limitation on the size of the complement; amendment to recite "full complement", e.g., would overcome this rejection.

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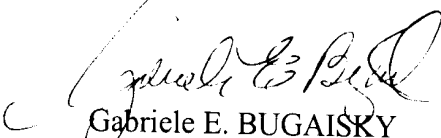
*Conclusion*

Claim 41 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

  
Gabriele E. BUGAISKY  
Primary Examiner  
Art Unit 1653

May 19, 2003